

117TH CONGRESS
2D SESSION

H. R. 7649

To direct the Secretary of Health and Human Services to open a public docket for the submission of public comments regarding factors that should be taken into consideration when reviewing a proposed modification to an approved risk evaluation and mitigation strategy, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

MAY 3, 2022

Mr. JOYCE of Pennsylvania (for himself, Ms. MATSUI, and Mr. GRIFFITH) introduced the following bill; which was referred to the Committee on Energy and Commerce

A BILL

To direct the Secretary of Health and Human Services to open a public docket for the submission of public comments regarding factors that should be taken into consideration when reviewing a proposed modification to an approved risk evaluation and mitigation strategy, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. PUBLIC DOCKET ON PROPOSED MODIFICA-**

2 **TIONS TO APPROVED STRATEGIES.**

3 (a) IN GENERAL.—Not later than 90 days after the
4 date of the enactment of this Act, the Secretary of Health
5 and Human Services shall open a public docket for the
6 submission of public comments regarding factors that
7 should be taken into consideration when a proposed modi-
8 fication to an approved risk evaluation and mitigation
9 strategy is reviewed under section 505–1(h) of the Federal
10 Food, Drug, and Cosmetic Act (21 U.S.C. 255–1(h)), in-
11 cluding factors related to patient access to the drug that
12 is the subject of the strategy and provider administration.
13 The Secretary may close such public docket not earlier
14 than 90 days after such docket is opened.

15 (b) GAO REPORT.—Not later than December 31,
16 2026, the Comptroller General of the United States shall
17 submit to the Committee on Energy and Commerce of the
18 House of Representatives and the Committee on Health,
19 Education, Labor, and Pensions of the Senate a report
20 on—

21 (1) the number of proposed modifications to an
22 approved risk evaluation and mitigation strategy the
23 Secretary has granted under section 505–1(h) of the
24 Federal Food, Drug, and Cosmetic Act (21 U.S.C.
25 255–1(h));

- 1 (2) any issues affecting patient access to the
2 drug that is the subject of the strategy or provider
3 administration that arose as a result of such modi-
4 fications; and
5 (3) how such issues were resolved, as applica-
6 ble.

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